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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/127,364 07/31/98 YEDNOCK

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EXAMINER

LUKTON, D

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

04/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/127,364

Applicant(s)

Yednock

Examiner

David Lukton

Group Art Unit

1653



☒ Responsive to communication(s) filed on Mar 15, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-10 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Pursuant to the directives of paper No. 12 (filed 3/15/01), claims 11-23 have been cancelled. Claims 1-10 remain pending.

Applicants have requested that the restriction be revised. Accordingly, this is done below:

Restriction to one of the following inventions is required under 35 U.S.C. §121:

Groups 1-17: defined as previously.

Group 18: Claims 1-10 drawn to compositions that contain compounds which are disclosed in application 08/904,424.

In their response filed 3/15/01, applicants have preemptively elected a group which corresponds to Group 18. The species election is also acknowledged, i.e:

Tos-Pro-Phe-OH

wherein the phenyl group of phenylalanine bears the group -O-CO-NMe₂.

*

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 or 18 of copending application Serial No. 09/126958. Although the conflicting claims are not identical, they are not patentably

distinct from each other. Instant claim 1 encompasses the compositions of claims 17 and 18 in the copending application.

[This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d)

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is asserted (page 19, line 20+) that compounds 1-9 induced the ligand occupied epitope 15/7 on the α_9 transfected cells at concentrations below 1 μ M. What the ligand occupied epitope was induced to do is not made clear. But in any case, there is no basis for recitation of the term "pharmaceutical" or "pharmaceutically" in the claims. These terms imply an assertion of therapeutic efficacy, which is not in evidence. It is suggested that applicants

delete the terms "pharmaceutical" or "pharmaceutically" from the claims. On the other hand, there is sufficient data in application 09/126958 to support the terms at issue. It is suggested that applicants submit a declaration which discloses the relevant data. In addition, or alternatively, the specification can be amended, to the extent that there is descriptive support in 60/112020. For example, on page 170, line 17+ of application 60/112020, IC₅₀ data was asserted. However, the data presented in this application, combined with that presented in application 09/126958 is not sufficient to support a claim, even a composition claim, which is drawn to a treatment of any and all "inflammatory conditions". It is suggested that the following phrase be deleted from claim 1:

"effective in treating an inflammatory condition".

*

Claims 1-10 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1 and 10 recite "inflammatory condition". Which are intended?
- Claim 2 recites that the inflammatory condition is characterized by increased neutrophil adhesion. To what are the neutrophils adhering?
- Claim 5 recites the phrase "less than about", thereby rendering the claim indefinite. It is suggested that "about" be deleted.
- Claim 9 recites that the compound is "selected for its ability to inhibit binding between *alpha*-9 integrin and an *alpha*-9 integrin ligand". The claim goes on to recite what would constitute an ideal potency. However, according to one

interpretation, all that is required is that one assess the binding. The claim does not require discarding a compound if it fails to be as potent as 1/1000 the potency of those listed. As long as the practitioner has assessed the "ability" of the compound, that is enough. For example, one could assess the "ability" of benzene to inhibit binding between *alpha*-9 integrin and an *alpha*-9 integrin ligand. Chances are, the "ability" of benzene to do this would not be very high; however, according to one interpretation, benzene would be included, even if it has no ability in the assay. It is suggested that the claim be amended to more affirmatively require a certain potency.

- In claim 10, the term "VCAM" should be spelled out, if it is going to be used

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1653